

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIODELIVERY SCIENCES INTERNATIONAL,)
INC. and)
ARIUS TWO, INC.,)

Plaintiffs,)

v.)

C.A. No. 18-1395 (CFC)

ALVOGEN PB RESEARCH & DEVELOPMENT)
LLC, ALVOGEN MALTA OPERATIONS LTD.,)
ALVOGEN PINE BROOK LLC, ALVOGEN,)
INC. and ALVOGEN GROUP, INC.,)

PUBLIC VERSION

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Defendants.)

**LETTER TO THE HONORABLE CHRISTOPHER J. BURKE FROM
JEREMY A. TIGAN REGARDING DISCOVERY DISPUTES**

OF COUNSEL:

Charles E. Lipsey
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, LLP
Two Freedom Square
11955 Freedom Drive
Reston, VA 20190-5675
(571) 203-2700

Jennifer S. Swan
Jeffrey D. Smyth
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, LLP
Stanford Research Park
3300 Hillview Avenue
Palo Alto, CA 94304-1203
(650) 849-6600

Howard W. Levine
Justin J. Hasford
Michael R. Galgano
Daniel G. Chung
Bonnie Fletcher Price
Daniele San Román
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, LLP
901 New York Avenue, NW
Washington, DC 20001-4413
(202) 408-4000

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MORRIS, NICHOLS, ARSHT & TUNNELL LLP
Jack B. Blumenfeld (#1014)
Jeremy A. Tigan (#5239)
1201 N. Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
jblumenfeld@mnat.com
jtigan@mnat.com

Attorneys for Plaintiffs

Dear Judge Burke:

Fact discovery in this case closed on February 3, 2020. And although fact discovery was briefly extended to March 27, 2020, the extension was for the limited purpose of completing “outstanding discovery issues.” (D.I. 126.) Alvogen, however, has used the extension as an excuse to inject new § 112 defenses and prior art references into this case, waiting until the last day of the extension period to serve amended contentions. Alvogen claims that its new theories and reliance on new prior art is timely. But this is not the first time Alvogen has belatedly added new invalidity grounds. Your Honor previously found that Alvogen’s addition of § 112 defenses based on the “layer” terms on February 3, the last day of the original fact discovery period, was “untimely.” (D.I. 143.) Accordingly, given Your Honor’s ruling, Alvogen cannot credibly claim that its attempt to add new theories and prior art nearly two months later, on March 27, 2020, is somehow timely or diligent.

Nor can Alvogen demonstrate any justification to excuse its delay. The extended discovery period did not reveal any new discovery that would warrant Alvogen amending its invalidity contentions. Rather, the prior art references that were added were available to Alvogen well before the close of fact discovery. And the § 112 theories are written description contentions based on the ’539 patent specification and prosecution history Alvogen has been aware of for at least two years. Accordingly, BDSI respectfully requests that the Court strike Alvogen’s late disclosed § 112 contentions and prior art references.

I. BACKGROUND

Alvogen served its initial invalidity contentions on May 29, 2019. (Ex. 1.) These contentions included numerous grounds for invalidity based on § 112, including lack of written description, enablement, and indefiniteness. (*Id.* at 152-62, 206-14, 253-73.) The contentions also referred to over 80 prior art references. (*Id.* at 26-117.)

Fact discovery closed on February 3, 2020. (D.I. 126.) That evening, Alvogen served supplemental invalidity contentions adding § 112 defenses based on the Court’s claim construction of the “layer” terms. (D.I. 135, Ex. 6.) BDSI sought relief from Your Honor to strike Alvogen’s newly added § 112 contentions. (D.I. 135.) Although the new contentions were deemed “untimely” and a “surprise[.]” to BDSI, after analyzing the *Pennypack* factors Your Honor declined to strike the contentions. (D.I. 143.)

Fact discovery was subsequently extended through March 27, 2020, but the parties agreed, and the Court ordered, that the extended discovery period “shall only be for the completion of outstanding discovery issues.” (D.I. 126 at ¶ 2.) Nevertheless, on the last day of the extended discovery period Alvogen served what it referred to as its “final” invalidity contentions, again adding new invalidity grounds and theories. (Ex. 2.) Alvogen stated that it included “additional references, information and/or arguments based on Alvogen’s ongoing investigation into the validity of the asserted patents.” (*Id.* at 6.)

Alvogen now seeks to assert 18 new prior art references in its invalidity contentions, including U.S. patent and patent application publications, non-patent literature, and Suboxone[®] sublingual film and Bunavail[®] buccal film products. (*Id.* at 6-7, 151-64). Alvogen identifies this “additional” prior art in Sections III.VVVV. – III.MMMMM. of the invalidity contentions. (*Id.*) And for the first time, Alvogen purports to add entirely new § 112 theories as “additional” arguments in Section VI.D.11. of its invalidity contentions. (*Id.* at 6-7, 402-03.) Alvogen asserts that the ’539

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patent does not reasonably convey to one of ordinary skill in the art that the inventors possessed the claimed “mild or moderate common opioid adverse effects, or no common opioid adverse effects” feature because the ’539 patent identifies that patients experienced “severe” adverse effects. (*See id.* at 402.) Alvogen further contends that the ’539 patent provides no guidance to one of ordinary skill in the art on how to optimize study results such that the “subject treated experiences mild or moderate common opioid adverse effects, or no common opioid adverse effects.” (*See id.* at 403.) Alvogen does not, however, articulate any reason for its delay in asserting these § 112 theories, let alone point to any new discovery obtained in February or March to justify the late supplement.

On April 24, 2020, BDSI requested that Alvogen withdraw the new prior art references and belated § 112 contentions. (Ex. 3.) During a meet-and-confer on May 18, 2020, Alvogen refused to withdraw its late contentions, insisting its contentions were “timely.” It also failed to explain why it raised the defenses so late.

II. ARGUMENT

Contrary to Alvogen’s assertions, its new § 112 theories are far from timely. Indeed, as Your Honor previously found, Alvogen’s “invalidity contentions still were required to be timely supplemented,” and Alvogen’s addition of new invalidity theories on February 3 “were not.” (D.I. 143.) For the same reasons, Alvogen’s attempts to further add new § 112 defenses and prior art references on March 27—almost two months later—are also untimely.

Alvogen cannot demonstrate any legally sufficient excuse for its belated invalidity grounds; they should have been raised months ago. Alvogen has long had the necessary information to raise these new arguments but simply delayed in doing so. All of the new prior art references were available to Alvogen well before the February 3 close of fact discovery. In fact, BDSI produced one of the references (the Aframian reference) on July 17, 2019, more than eight months ago, and another reference (U.S. 2011/0033541) was cited on the faces of the ’843 and ’539 patents. As for the new § 112 defenses, Alvogen relies on only the ’539 patent specification and prosecution history. None of these new prior art references or § 112 theories are based on the recent discovery of material information. Indeed, during the parties’ meet-and-confer, Alvogen was unable to point to any new discovery learned during the extension period that would now warrant asserting the new prior art and § 112 contentions.

Because fact discovery under the scheduling order ended on February 3, 2020, Alvogen was required to make a showing of “good cause” and diligence to add the new theories, which it has failed to do. *See St. Clair Intellectual Prop. Consultants, Inc. v. Matsushita Elec. Indus. Co., Ltd.*, No. 04-1436-LPS, 2012 WL 1015993, at *5-7 (D. Del. Mar. 26, 2012); *Silver State Intellectual Techs., Inc. v. Garmin Int’l, Inc.*, 32 F. Supp. 3d 1155, 1166 (D. Nev. 2014) (striking new § 112 contentions for lack of diligence where defendant could not demonstrate what “opened the door to the amended legal arguments of invalidity” or why defendant “could not have anticipated these invalidity contentions”). Alvogen has had access to everything it needed to make these arguments months, or even years, ago, and there is no justification for its delay.

Further, the *Pennypack* factors favor precluding Alvogen from relying on its untimely contentions. Although fact discovery was extended through March 27, the extension was only to complete unfinished discovery. The extension did not permit the parties to raise completely new theories or assert new prior art, as Alvogen attempts to do here. This alone is grounds to strike

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Alvogen's untimely contentions. *See, e.g., Praxair, Inc. v. ATMI, Inc.*, 231 F.R.D. 457, 464 (D. Del. 2005) (applying the *Pennypack* factors and striking invalidity defenses based on new prior art references disclosed during discovery extension period because the extension "was to bring closure to open discovery issues, not to open new discovery issues"), *rev'd and remanded on other grounds*, 543 F.3d 1306 (Fed. Cir. 2008); *Bridgestone Sports Co. Ltd. v. Acushnet Co.*, No. 05-132-JJF, 2007 WL 521894, at *4 (D. Del. Feb. 15, 2007) (precluding defendant from relying on untimely disclosed prior art references under the *Pennypack* factors where "any lack of diligence by [defendant] is insufficient to excuse its delay").

BDSI would be prejudiced by allowing Alvogen to rely on these untimely defenses because they were improperly raised two months after fact discovery closed, precluding BDSI from conducting additional fact discovery to formulate a proper response. *See Bridgestone*, 2007 WL 521894 at *5; *Fairchild Semiconductor Corp. v. Power Integrations, Inc.*, No. 12-540-LPS, 2015 WL 1883960, at *2 n.2 (D. Del. Apr. 24, 2015). Concerning the "willfulness" factor, this is not the first time Alvogen has delayed raising new invalidity theories and positions, and Alvogen has not offered any explanation why it raised these theories and prior art references so late. *See Guardant Health, Inc. v. Found. Med., Inc.*, No. 17-1616-LPS-CJB, D.I. 423 (D. Del. April 28, 2020) (precluding use of a late-disclosed witness and noting that "this is the second time that the Court has found that FMI made late disclosures in violation of Rule 26(a)(1)(A)") (attached as Exhibit 4). And finally, prior to March 27, Alvogen already served some 400 pages of invalidity contentions, including the 80-plus prior art references disclosed in its initial contentions—it need not rely on belated theories and prior art. As Your Honor has stated, "though the *Pennypack* factors may be very forgiving, they are not a sieve." *Id.* The new theories and prior art references should be stricken.

Respectfully,

/s/ Jeremy A. Tigan

Jeremy A. Tigan (#5239)

cc: All Counsel of Record (via CM/ECF and e-mail)